Complete Summary

GUIDELINE TITLE

Osteoporosis prevention, diagnosis, and therapy.

BIBLIOGRAPHIC SOURCE(S)

Osteoporosis prevention, diagnosis, and therapy. NIH Consens Statement Online 2000 Mar 27-29;17(1):1-36.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Osteoporosis

GUIDELINE CATEGORY

Diagnosis
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Physical Medicine and Rehabilitation
Preventive Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To address the following key questions:

- What is osteoporosis and what are its consequences?
- How do risks vary among different segments of the population?
- What factors are involved in building and maintaining skeletal health throughout life?
- What is the optimal evaluation and treatment of osteoporosis and fractures?
- What are the directions for future research?

TARGET POPULATION

Adults (including residents of long-term care facilities), adolescents and children at risk for or diagnosed with osteoporosis.

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment/Prognosis

1. Bone density
2. Other risk factors

Diagnosis

1. Bone mineral density measurements using dual energy x-ray absorptiometry (DXA) or quantitative ultrasound (QUS)

Treatment/Prevention

1. Calcium and vitamin D intake
2. Physical activity (exercise)
3. Cyclic etidronate, alendronate, risedronate (bisphosphonates)
4. Hormone replacement therapy
5. Selective estrogen receptor modulators, such as raloxifene
6. Natural estrogens, particularly plant-derived phytoestrogens
7. Salmon calcitonin
8. Nonpharmacologic interventions (directed at preventing falls and reducing effect on fractures)

MAJOR OUTCOMES CONSIDERED

- Bone mineral density
- Fracture risk
- Fracture rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature was searched through electronic databases including MEDLINE (National Library of Medicine [NLM]), and an extensive bibliography of references was provided to the panel and the conference audience. Experts prepared abstracts with relevant citations from the literature. Scientific evidence was given precedence over clinical anecdotal experience.

A comprehensive bibliography of recent literature on the Consensus Conference and Technology Assessment Workshop topics is prepared by the Reference Section of the NLM prior to each Consensus Development Conference or Workshop. Copies are provided to the Consensus Panel prior to the conference and to all other participants, including the audience, at the conference/workshop. These bibliographies are prepared as part of the NLM Current Bibliographies in Medicine series (See "Availability of Companion Documents").

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Scientific evidence was given precedence over clinical anecdotal experience.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The National Institutes of Health (NIH) Consensus Development Panel for Osteoporosis Prevention, Diagnosis, and Therapy, answering predefined questions, developed their conclusions based on the scientific evidence presented in open forum and the scientific literature. The panel composed a draft statement that was read in its entirety and circulated to the experts and the audience for comment. Thereafter, the panel resolved conflicting recommendations and released a revised statement at the end of the conference.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The National Institutes of Health (NIH) Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy finalized the revisions within a few weeks after the conference. The draft statement was made available on the World Wide Web immediately following its release at the conference and was updated with the panel's final revisions.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Question 1: What is osteoporosis and what are its consequences?

- Osteoporosis occurs in all populations and at all ages. Though more prevalent in white postmenopausal females, it often goes unrecognized in other populations.
- Osteoporosis is a devastating disorder with significant physical, psychosocial, and financial consequences.

Question 2: How do risks vary among different segments of the population?

- The risks for osteoporosis, as reflected by low bone density, and the risks for fracture overlap but are not identical.
- More attention should be paid to skeletal health in persons with conditions known to be associated with secondary osteoporosis.

- Clinical risk factors have an important, but as yet poorly validated, role in determining who should have bone mineral density (BMD) measurement, in assessing risk of fracture, and in determining who should be treated.

Question 3: What factors are involved in building and maintaining skeletal health throughout life?

- Adequate calcium and vitamin D intake are crucial to develop optimal peak bone mass and to preserve bone mass throughout life. Supplementation of these two components in bioavailable forms may be necessary in individuals who do not achieve recommended intake from dietary sources.
- Gonadal steroids are important determinants of peak and lifetime bone mass in men, women, and children.
- Regular exercise, especially resistance and high-impact activities, contributes to development of high peak bone mass and may reduce the risk of falls in older individuals.

Question 4: What is the optimal evaluation and treatment of osteoporosis and fractures?

- Assessment of bone mass, identification of fracture risk, and determination of who should be treated are the optimal goals when evaluating patients for osteoporosis.
- Fracture prevention is the primary goal in the treatment of patients with osteoporosis.
- Several treatments have been shown to reduce the risk of osteoporotic fractures. These include therapies that enhance bone mass and reduce risk or consequences of falls.
- Adults with vertebral, rib, hip, or distal forearm fractures should be evaluated for the presence of osteoporosis and given appropriate therapy.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The panel, answering predefined questions, developed their conclusions based on a comprehensive review of scientific evidence presented in open forum and the scientific literature.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Calcium and vitamin D intake modulates age-related increases in parathyroid hormone (PTH) levels and bone resorption. Randomized clinical trials have demonstrated that adequate calcium intake from diet or supplements increase

spine bone mineral density (BMD) and reduce vertebral and nonvertebral fractures. Low levels of 25-OH vitamin D are common in the aging population, and significant reductions in hip and other nonvertebral fractures have been observed in patients receiving calcium and vitamin D3 in prospective trials.

- Physical activity is necessary for bone acquisition and maintenance through adulthood. Trials of exercise intervention show most of the effect during skeletal growth and in very inactive adults. Effects beyond those directly on bone, such as improved muscular strength and balance, may be very significant in fracture-risk reduction. Trials in older adults have successfully used various forms of exercise to reduce falls. High-impact exercise (weight training) stimulates accrual of bone mineral content in the skeleton.
- Randomized placebo-controlled trials (RCTs) of cyclic etidronate, alendronate, and risedronate analyzed by a systematic review and meta-analysis have revealed that all of these bisphosphonates increase BMD at the spine and hip in a dose-dependent manner. They consistently reduce the risk of vertebral fractures by 30 to 50 percent. Alendronate and risedronate reduce the risk of subsequent nonvertebral fractures in women with osteoporosis and adults with glucocorticoid-induced osteoporosis.
- Hormone replacement therapy (HRT) is an established approach for osteoporosis treatment and prevention. Many short-term studies and some longer term studies with BMD as the primary outcome have shown significant efficacy. Observational studies have indicated a significant hip fracture reduction in cohorts of women who maintain HRT therapy. HRT trials have shown decreased risk of vertebral fractures.
- Raloxifene, a selective estrogen receptor modulator (SERM) approved by the Food and Drug Administration (FDA) for the treatment and prevention of osteoporosis, has been shown to reduce the risks of vertebral fracture by 36 percent in large clinical trials. Tamoxifen, used in the treatment and prevention of breast cancer, can maintain bone mass in postmenopausal women. However, effects on fracture are unclear.
- Salmon calcitonin has demonstrated positive effects on BMD at the lumbar spine, but this effect is less clear at the hip.
- Nonpharmacologic interventions directed at preventing falls and reducing their effect on fractures have been promising. These include studies to improve strength and balance in the elderly, as well as using hip protectors to absorb or deflect the impact of a fall.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This statement is an independent report of the panel and is not a policy statement of the National Institutes of Health (NIH) or the Federal Government.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Osteoporosis prevention, diagnosis, and therapy. NIH Consens Statement Online 2000 Mar 27-29;17(1):1-36.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Mar 27-29

GUIDELINE DEVELOPER(S)

National Institutes of Health (NIH) Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy - Independent Expert Panel

GUIDELINE DEVELOPER COMMENT

National Institutes of Health (NIH) Consensus Statements are prepared by a nonadvocate, non-Federal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session (2) questions and statements from conference attendees during open discussion periods that are part of the public session and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the consensus panel and is not a policy statement of the NIH or the Federal Government.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

National Institutes of Health (NIH) Consensus Development Panel for Osteoporosis Prevention, Diagnosis, and Therapy

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Consensus Development Panel: Anne Klibanski, M.D., Panel and Conference Chair; Lucile Adams-Campbell, Ph.D.; Tamsen Bassford, M.D.; Steven N. Blair, P.E.D.; Scott D. Boden, M.D.; Kay Dickersin, Ph.D.; David R. Gifford, M.D., M.P.H; Lou Glasse, M.S.W.; Steven R. Goldring, M.D.; Keith Hruska, M.D.; Ira M. Lang; Susan R. Johnson, M.D., M.S.; Laurie K. McCauley, D.D.S., Ph.D.; William E. Russell, M.D.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All of the panelists who participated in the National Institutes of Health (NIH) conference and contributed to the writing of this consensus statement were identified as having no financial or scientific conflict of interest, and all signed conflict of interest forms attesting to this fact.

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the National Institutes of Health (NIH) Consensus Development Conference Program Web site. Also available from the National Library of Medicine Health Services/Technology Assessment Text (HSTAT) Web site.

Print copies: Available from the NIH Consensus Development Program Information Center, PO Box 2577, Kensington, MD 20891; Toll free phone (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); autofax (in U.S.), 1-888-NIH-CONSENSUS (1-888-644-2667); e-mail: consensus_statements@mail.nih.gov.

AVAILABILITY OF COMPANION DOCUMENTS

A complete bibliography prepared by the National Library of Medicine (NLM) is available at the NLM Web site.

In addition, a program and abstract book is available at the NIH Consensus Development Conference Program Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on September 25, 2000. The information was verified by the guideline developer on October 10, 2000.

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